



FIT Test Reproducibility

The KBMO Food Inflammation Test was invented by Dr. Brent Dorval. Dr. Dorval is a very accomplished scientist, having received his PhD from MIT and is credited with inventing the first Rapid HIV diagnostic laboratory test. Under Dr. Dorval's leadership, our approach to quality, accuracy and reproducibility has been based on our roots in the HIV testing arena, where there is no room for error. We manufacture the kits in house to ensure maximal quality control and conform to the most rigid ISO and FDA standards. We are the only company to have received COFEPRIS and AMVISA regulatory approvals to be able to ship the kits into both Mexico and Brazil. Each test is run on 3 ELISA plates with 15 standards and controls to ensure the highest levels of accuracy and reproducibility. Since no human standards or controls exist for each of the 132 foods colorings and additives that we run, Sensitivity and Specificity is ensured through the 15 procedural standards and controls that we have on the plate.

Our test kit manufacturing facility is FDA registered, ensuring that any new lot is run in parallel with a lot that has been already qualified. The results must match FDA standards to pass qualification. If a new lot fails to reach these conditions then the lot is rejected, ensuring that all kits are produced in the same way and yield the same results every time, therefore producing a quality product we can trust.

As a CLIA certified lab, we track reproducibility in two ways, through reagent qualification and proficiency testing. In reagent qualification, each new lot of reagent gets qualified by running 6 samples on the current lot and again on the new lot. This is performed on six samples on at least a monthly basis. Two of those samples are from a frozen serum pool which allows us to track reproducibility for up to 12 months on the same sample. This way we can monitor for any subtle shifts or trends in the antigens over time. Proficiency testing is also used to monitor reproducibility. Every 6 months each laboratory technologist must match every other tech in the lab on two samples reproduced independently. This not only ensures that the reagents used produce consistent results but that each laboratory technologist produce the same results. We test at least 140 duplicate samples each year as part of this and they all pass our internal criteria.

Summary:

The FIT test was performed on two samples over the course of 9 months for a total of 60 times, an average of approximately 7 times a month. The testing coincided with new reagent lot qualification. The first sample had a reproducibility of 99.1%. The second sample had a reproducibility of 98.6%.

